IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); APTALIS PHARMA US, INC. (a Delaware corporation); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company),

Plaintiffs,

v.

LIZ MURRILL, in her official capacity as the Attorney General of the State of Louisiana,

Defendant.

No. 6:23-CV-01307

Judge Robert R. Summerhays

Magistrate Judge Carol B. Whitehurst

PLAINTIFFS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US, Inc., Pharmacyclics LLC, Allergan Sales, LLC (collectively "AbbVie" or "Plaintiffs"), by and through their undersigned attorneys, respectfully submit this Memorandum of Law in Support of their Motion for Summary Judgment, and in support thereof states as follows:

INTRODUCTION

This lawsuit seeks to enjoin Louisiana's unconstitutional attempt to change the requirements of a federal program, interfere with the exclusive authority of federal regulators, undo a federal court's interpretation of a federal statute, and order the transfer of private property from drug manufacturers to commercial, for-profit pharmacies. In 1992, Congress created the federal 340B drug program, which requires manufacturers—as a condition of participation in Medicare and Medicaid—to offer certain of their drugs, at below-cost prices, to particular kinds of non-profit entities serving the poor referred to as "covered entities." In recent decades, however, covered entities have abused the program and violated its requirements. Instead of using discounted drugs to treat poor and uninsured patients, they have turned the program into a profit-making arbitrage scheme. In particular, they have sought to share their statutory right to access heavily discounted drugs with for-profit commercial pharmacies—even though Congress deliberately excluded such pharmacies from participating in the 340B program and limited the program's scope to helping patients by prohibiting the diversion of 340B benefits to anyone else. What happens is this: A covered entity agrees to allow a commercial pharmacy, such as CVS or Walgreens, to serve as its "contract pharmacy" for dispensing 340B discounted drugs; the pharmacy then obtains the 340B drugs from manufacturers at below market prices (often for pennies), sells the drugs to patients at full market price, and splits the windfall profit with the covered entity. While covered entities and their contract pharmacies pocket billions that Congress never intended, patients and manufacturers alike both lose.

Litigation has raged around the country about the legality of these "contract pharmacy" arrangements. The Third Circuit recently confirmed that the 340B statute does *not* require manufacturers to deliver drugs at 340B discounted prices to contract pharmacies. *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 707 (3d Cir. 2023). ("Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies."). Congress did not give contract pharmacies a right to benefit from the federal program and access drugs at 340B discounted prices. Nor did Congress make transferring discounted drugs to pharmacies a condition of manufacturers' participation in Medicare and Medicaid.

In response, Louisiana—an *amicus curiae* on the losing side in the Third Circuit—passed Act 358 seeking to impose its own view of the federal 340B program as a matter of state law. The Act refers to the federal 340B program by name and could not exist but for that program. It expressly seeks to change the requirements of federal law—and hence the conditions of participation in Medicare and Medicaid—by mandating that *drugs discounted under that federal program* must be delivered to contract pharmacies on demand, without "interference" from manufacturers.

Act 358 is unconstitutional. *First*, it is preempted. Act 358 intrudes on an exclusively federal field of regulation—a field Congress *invented* and then gave a federal agency exclusive authority to superintend and enforce. *Astra USA, Inc. v. Santa Clara Cnty., CA*, 563 U.S. 110, 120-21 (2011). Unsurprisingly, Act 358 conflicts with Congress's goals and objectives in setting up that program: the price of participation in Medicare and Medicaid, who gets to benefit from the sale of manufacturers' drugs at discounted 340B prices, and who gets to enforce the program's rules. *Second*, Act 358 effects an unconstitutional taking. It requires drug manufacturers to give

their property to other private parties, for free, and not for any recognized public use. And unlike the federal government, Louisiana is not *paying* for that concession through access to a benefits program; Act 358 is just a direct command to take property from A and give it to B—the most plain form of an unconstitutional taking. *See Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798). *Third*, the language of Act 358 is incomprehensible and void for vagueness.

The Act should be permanently enjoined.

BACKGROUND

Section 340B and Pharmaceutical Manufacturers

Before the early 1990s, individual drug manufacturers voluntarily provided their drugs at reduced prices to certain institutions serving needy and vulnerable patient populations. In 1992, by enacting the Medicaid Rebate Act, Congress inadvertently made those charitable efforts prohibitively costly. H.R. Rep. No. 102-384, pt. 2, at 9–10 (1992). In response, Congress enacted Section 340B of the federal Public Health Service Act, 42 U.S.C. § 256b *et seq.*, which established what is commonly called the federal "340B program."

The 340B program aims to help uninsured, low-income patients by providing them with better access to prescription medications at deeply discounted prices. Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015). Transforming manufacturers' charitable commitments into a statutory prerogative, Congress made compliance with the 340B statute a condition of any manufacturer's participation in the federal Medicaid and Medicare Part B programs, which account for nearly half of the nation's drug market. To continue selling their drugs to millions of low-income and elderly patients, manufacturers are forced to offer their covered outpatient drugs at deeply discounted prices to an enumerated list of "covered entities." 42 U.S.C. § 256b(a)(4).

Manufacturers enter the 340B program when they sign a form contract, called the Pharmaceutical Pricing Agreement ("PPA"), with the United States Department of Health and Human Services ("HHS"). *See Astra*, 563 U.S. at 113. The PPA, which is drafted by HHS, is the federal contract used to implement the 340B statute. It contains "no negotiable terms" and "incorporate[s] the statutory obligations and record[s] the manufacturers' agreement to abide by them." *Id.* at 117–18.

As reflected in the PPA, the 340B statute requires manufacturers to sell their products at substantial discounts to covered entities for the benefit of indigent and uninsured patients. The statute states that manufacturers "shall . . . offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). A statutory formula establishes the "ceiling price" for covered drugs, *id.* § 256b(a)(1)–(2) & (b), which results in prices *significantly* below the market value of manufacturers' drugs. Under the 340B program, all but a few innovator drugs are subject to discounts ranging from 23.1% to more than 99.9% of the average market price. *Id.* § 256b(a)(1); *id.* § 1396r-8(c). Many mandatory 340B ceiling prices are as little as *one penny* per unit of drug—effectively a giveaway. *See* SOF ¶ 19.

No doubt because of the constitutional dangers and risks of abuse inherent in this novel scheme, Congress carefully limited the 340B program and manufacturers' obligations. Most importantly, the statute restricts which entities are able to participate in the program and benefit from the sale of manufacturers' discounted drugs. The statute narrowly defines "covered entities" to include only certain enumerated types of non-profit organizations that were established to serve predominantly low-income and uninsured patients. Covered entities include federally qualified health centers, children's hospitals, qualifying rural hospitals, and certain federally funded clinics

that vulnerable patients visit to receive healthcare services. *Id.* § 256b(a)(4). No for-profit entity appears on Congress's list. Nor is there any catchall provision sweeping in other organizations that may be similar to those that Congress named. *See id.*; *see also id*. § 256b(a)(6) (providing that when a covered entity is "a distinct part of a hospital," the hospital itself "shall not be considered a covered entity").

Because the 340B statute is intended to benefit vulnerable patients and not the covered entities themselves, its provisions forbid covered entities from realizing windfalls or benefits unauthorized by the 340B program. The statute expressly prohibits, for example, "diversion" and "duplicate discounts." *Id.* § 256b(a)(5)(B). "Diversion" occurs when a covered entity sells or otherwise transfers a manufacturer's discounted drugs "to a person who is not a patient of the entity." *Id.*; *see also id.* § 256b(a)(8) (defining narrow circumstances, established by the Health Resources and Services Administration, when a covered entity may "enter into contracts with prime vendors for the distribution" of manufacturers' 340B drugs). The statute's diversion prohibition is consistent with the program's purpose: to serve the poor and uninsured patients of the qualifying covered entity itself, and to avoid allowing others to profit or benefit from the sale or transfer of manufacturers' drugs at discounted prices. Covered entities are similarly barred from generating "duplicate discounts or rebates," by obtaining both a 340B discount on a drug and also submitting such unit for reimbursement to Medicaid. *Id.* § 256(a)(5)(A). Recognizing the temptation for covered entities to take advantage of the program, the statute imposes an affirmative duty on the Secretary of HHS—through authority delegated to the Health Resources and Services Administration ("HRSA")—to protect the program's integrity. *E.g.*, *id.* § 256b(d)(2)(A) ("provid[ing] for improvements in compliance by covered entities . . . in order to prevent diversion" and violations of the statute's duplicate discount prohibition).

Congress vested HHS with exclusive authority to enforce the 340B program's rules, while also denying HHS any authority to change the scope of the program by creating new rights for covered entities or by imposing new obligations on manufacturers. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 42–43 (D.D.C. 2014) ("*PhRMA*") (explaining that HHS lacks "broad rulemaking authority" under the 340B statute). The 340B statute prescribes a comprehensive set of mechanisms for resolving administrative disputes between manufacturers and covered entities, including through audits and a federal Administrative Dispute Resolution ("ADR") process conducted before a special federal tribunal. 42 U.S.C. § 256b(d)(1)(B)(v), (d)(3). The statute also gives the HHS Secretary, through HRSA, exclusive enforcement authority. *Id.* § 256b(a)(5)(C)–(D), (d)(1)(B)(v), (d)(3). Failure to comply with the 340B program's statutory requirements may result in termination of the PPA (and thus of the manufacturer's ability to participate in Medicaid), federal enforcement actions, and imposition of large civil penalties. *Id.* § 256b(a)(5)(D), (d)(1)(B)(vi), (d)(2)(B)(v), (d)(3)(A).

The Rise Of "Contract Pharmacies"

Taking advantage of non-binding guidance documents, covered entities have attempted to expand the scope of manufacturers' obligations under the 340B program for their own financial benefit. As a result of abuses, the 340B program has grown at an astronomical pace.

It began innocently enough: When Congress created the 340B program, it was designed to ensure that covered entities operating an in-house pharmacy would have access to discounted drugs to provide to the poor patients who visited their facilities. In 1996, four years after Congress created the 340B program, however, more covered entities pushed to participate in the program. In response, HHS issued a non-binding guidance addressing how covered entities could order discounted drugs from manufacturers if they did not have an in-house pharmacy to receive them. The agency opined that covered entities without an in-house pharmacy could—without running

afoul of the statutory prohibition on diversion—enter into a contractual relationship with a *single* outside pharmacy to dispense covered outpatient 340B-priced drugs to its patients, but only if the covered entity maintained title to the drugs and the outside pharmacy kept them in a segregated inventory. *See* 61 Fed. Reg. 43,549, 43553 (Aug. 23, 1996) ("Because the covered entity purchases the drug, retaining title, and directs shipment to its contractor, it retains responsibility for the drug. If the drug generates a Medicaid rebate or is diverted to an individual who is not a patient of the covered entity, the entity will be responsible for such activity."). Accordingly, when a covered entity treated an uninsured or underinsured patient, the patient could access manufacturers' discounted drugs by filling his or her prescription at either the covered entity's in-house pharmacy or at the pharmacy across the street that served as the equivalent of an in-house pharmacy.

Fourteen years later, in 2010, the agency issued another non-binding guidance that resulted in radical changes to the 340B program. This time, the agency announced that it would allow covered entities to enter into contractual relationships with an *unlimited number* of "contract pharmacies," and to do so even if the covered entity had an in-house pharmacy of its own. 75 Fed. Reg. 10,272, 10273 (March 5, 2010). The agency took the view that if a patient visited a covered entity for healthcare services, it could be more convenient for the patient to fill any prescription resulting from that visit at his or her local pharmacy. The agency's guidance still provided that covered entities would be required to maintain title until dispensing and suggested maintaining discounted drugs in a segregated inventory in order to satisfy that obligation. *Id.* at 10278 (covered entity must make the "purchase;" and "maintain title" to the drugs until they were dispensed to eligible patients; and "assume responsibility for establishing [the] price" charged to their patients).

Significantly, although both the 1996 and 2010 guidance documents addressed what covered entities could do, they were not binding and did not purport to say what manufacturers

must do. Importantly, the agency did not claim that the 340B statute itself required manufacturers to cooperate with these so-called "contract pharmacy" arrangements. 61 Fed. Reg. 43,549, 43550 (Aug. 23, 1996) ("creat[ing] no new law and creat[ing] no new rights or duties"); 74 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (same).

Covered entities took advantage of the 2010 guidance in a way that resulted in an explosion in the 340B program and a proliferation of abuses. Instead of using manufacturers' drugs to benefit needy patients, covered entities saw in the 2010 guidance an opportunity for arbitrage. By entering contractual arrangements with numerous pharmacies—often located long distances from the covered entity itself—covered entities have been able to generate windfall profits by selling manufacturers' discounted drugs to pharmacy customers instead of using them for the benefit of the covered entities' indigent and uninsured patients. As a result of these contractual arrangements, for-profit commercial pharmacies like CVS and Walgreens have obtained massive amounts of manufacturers' drugs for pennies; sold them to their customers at full price; and then split the profits with the covered entity.

Contract pharmacies execute this arbitrage scheme through something called the "replenishment model," a model unique to the federal 340B program. Under this model, the dispensing of 340B drugs to a covered entity patient is a fiction. A commercial contract pharmacy typically dispenses drugs to all its customers from the pharmacy's general inventory of drugs; some of which were not obtained through the 340B program but instead ordinary commercial purchases. SOF ¶ 46. The contract pharmacy later determines how much of its stock it thinks it has dispensed to customers who might have at one time been patients of a covered entity. The covered entity then demands that the manufacturer transfer additional quantities of the drug at the federal 340B discounted price to the contract pharmacy to "replenish" the non-340B drugs that the

pharmacy has dispensed. *See* Ex. 2, June 16, 2021 Declaration of RADM Krista M. Pedley, Director, Office of Pharmacy Affairs, HRSA, at ¶¶ 3–11; SOF ¶ 46 & n.39. Surprisingly, a covered entity might not even aware that the pharmacy is placing this "replenishment" order as the pharmacy (or its third-party vendor) often places such order. At the end of this complicated accounting mechanism—which is used exclusively in the context of the federal 340B program by covered entities and their pharmacy contracting partners—the value of manufacturers' medicines is transferred to private, for-profit parties.

The public has not benefitted from this arbitrage scheme. For starters, poor patients do not get cheap drugs—commercial pharmacies do.[1] Other than in very rare cases, patients are indifferent about whether they obtain drugs at contract pharmacies because they charge patients (and their insurance companies) the same full price as every other pharmacy. *See* Rory Martin, White Paper: Are Discounts in the 340B Drug Discount Program Being Shared with Patients at

[1] *See* HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: Contract Pharmacy Arrangements in the 340B Program (2014) ("HHS Report"), at 2, https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, WALL ST. J. (Sept. 10, 2020), https://www.wsj.com/articles/the-federal-program-that-keeps-insulin-prices-high-11599779400 (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which is designed as a narrow support to certain hospitals," while patients "don't benefit," even though manufacturers have "practically given the product away"); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, IQVIA, at 12, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf ("The 340B Drug Discount Program as it exists today is a complex system of arbitrage . . . in which most vulnerable patients at contract pharmacies do not get drug discounts."); Lin JK, et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum (2022), at 2, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530 (finding that contract pharmacy growth from 2011–2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

Contract Pharmacies, at 9 (IQVIA Mkt. Access Ctr. Of Excellence 2022) (citing evidence suggesting that patients receive discounts at contract pharmacies less than 1.4% of the time).

Meanwhile, HHS's Inspector General has made clear that contract-pharmacy arrangements create a significantly greater risk that manufacturers' discounted drugs will be dispensed to pharmacy customers who are not "patients" of the covered entity. *See* HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: Contract Pharmacy Arrangements in the 340B Program (2014) ("HHS Report"), at 1, https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp. HHS's Inspector General has concluded that contract pharmacy arrangements "create complications in preventing diversion," because, for example, contract pharmacies cannot verify patient eligibility in real-time. *Id.* In fact, because contract pharmacies often dispense 340B covered outpatient drugs from the same inventory as drugs dispensed to all other customers, the opportunities for unlawful distributions to ineligible patients increases—allowing covered entities and their contract pharmacies to profit from the very diversion that Congress intended to prohibit. *See* GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, at 28 (Sept. 2011), https://www.gao.gov/products/gao-11-836; GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 35, 43–44 (June 2018), https://www.gao.gov/products/gao-18-480 (finding 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies; and many of the remaining 55% reported rarely giving discounts to patients obtaining medicines through contract pharmacies); *id.* at 44 (explaining "66 percent of . . . diversion findings in HRSA audits involved drugs distributed at contract pharmacies"). In the last decade, covered entities' use of contract pharmacies has increased by more than *4,200% percent*. SOF ¶ 42. And the arbitrage profits have

been enormous. One study found that in 2018 alone, covered entities and their contract pharmacies generated more than $13 billion in estimated gross profits from selling manufacturers' drugs purchased at the discounted 340B price to pharmacy customers at full prices. SOF ¶ 42. Tellingly, when manufacturers later tried to stop this scheme, both CVS Pharmacy[2] and Walgreens, Inc.[3] listed manufacturers' revised 340B policies as a *material risk to their business. If manufacturers stopped transferring virtually unlimited amounts of 340B discounted drugs to contract pharmacies, the pharmacies stood to lose out on a significant profit stream. In short, supported by no action from Congress, drug benefits that were supposed to be carefully channeled into the hands of non-profit entities for the benefit of poor patients have become a profit center for commercial enterprises; and the 340B program has become the largest federal drug program in existence, except for Medicare Part D, and will soon eclipse even that program. See* Alliance for Integrity and Reform of 340B*, The Impact of Growth in 340B Contract Pharmacy Arrangements—Six Years Later*, at 8 (Oct. 2020), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/ https://340breform.org/wp-content/uploads/2021/04/AIR340B_340B-Contract-Pharmacies.pdf. Manufacturers Adopt Policies to Address 340B Abuses.

In 2020, after watching the arbitrage scheme and 340B program abuses spiral out of control, a number of drug manufacturers decided to take steps to restore the program's integrity. Some returned to the basic model that emerged after HRSA's 1996 guidance, agreeing that covered entities without an in-house pharmacy could use a single contract pharmacy to receive 340B drugs.

[2] *See* CVS Pharmacy 10-K (2022) at 22 ("A reduction in Covered Entities participation in contract pharmacy arrangement, … or a reduction in drug manufacturers' participation in the program could materially and adversely affect the Company.").

[3] Walgreens, Inc. 10-K at 28 (2022) ("Changes in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B drug pricing program, could also significantly reduce our profitability.").

These policies tried to ensure that manufacturers' discounted drugs would be used for the benefit of the needy patients who visited the facilities of covered entities; the manufacturers refused requests by covered entities to facilitate the transfer of their drugs at discounted prices to an unlimited number of contract pharmacies. SOF ¶ 54. Others agreed to recognize multiple contract pharmacies, but only if the covered entity provided sales data that would allow the manufacturer to ensure 340B discounts were not being diverted or the subject of duplicate discounts. SOF ¶ 54.

In March 2023, AbbVie[4] announced its current 340B program integrity initiative, which prohibits hospital covered entities from directing that AbbVie's 340B priced drugs be transferred to contract pharmacies, unless that hospital covered entity does not have an in-house pharmacy and it selects a contract pharmacy within 40 miles of that hospital covered entity's location while providing limited data for the one contract pharmacy. SOF ¶¶ 55, 56. Federal grantees are excepted from this policy. SOF ¶ 56. AbbVie continues to offer unlimited 340B drugs to any covered entity that wants to buy them, as the 340B statute requires. *See Sanofi Aventis*, 58 F.4th at 703 ("Even if drug makers limit where they will deliver drugs, they still present the drugs for covered entities' acceptance. And the drug maker's delivery conditions do not prevent any covered entity from accepting these offers. Each can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy."). Accordingly, AbbVie's policy in no way affects patient access to 340B drugs. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's discounted 340B drugs to qualifying patients. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40

[4] Ex. 1, January 12, 2024, Declaration of Edward Scheidler ("Scheidler Declaration"), ¶ 13; SOF ¶¶ 1–7.

miles, AbbVie will work with the covered entity to identify a suitable alternative. SOF ¶ 57. But AbbVie will not indiscriminately accept requests to transfer 340B discounted drugs to an unlimited number of commercial pharmacies that have entered contracts with hospital covered entities. *Id.*

The Third Circuit Rules in Favor of Manufacturers

HHS initially recognized that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies. *See* Tom Mirga, *HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), https://340breport.com/hrsa-says-its-340b-contract-pharmacy/. That position was consistent with the agency's guidance documents described above, none of which purported to expand manufacturers' obligations. Since HRSA has no substantive rulemaking authority in this area, *PhRMA*, 43 F. Supp. 3d at 42, if no such obligation is found in the statute, it does not exist.

In December 2020, HHS changed its mind. The agency issued a final decision—labeled an "Advisory Opinion"—that for the first time purported to require manufacturers to facilitate the transfer of their products to for-profit commercial pharmacies. *See* HHS, Advisory Opinion No. 20-06, Contract Pharmacies Under the 340B Program (Dec. 30, 2020), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf. The 2020 Advisory Opinion claimed that this obligation was *unambiguously required* by the language of the federal 340B statute.

Litigation ensued. A number of manufacturers sued HHS in district courts around the country, first over the Advisory Opinion and later over enforcement letters the agency sent them, purporting to find their 340B distribution policies in violation of the agency's new statutory

interpretation.[5] The manufacturers argued that the 340B statute requires only that they offer their drugs to covered entities at discounted prices; it does not require them also to deliver the discounted drugs to an unlimited number of contract pharmacies; nor does the statute prohibit *any* reasonable commercial conditions on offers for sale. The 340B program is supposed to be for the benefit of needy patients; it is not designed to line the pockets of covered entities and their contract pharmacies.

Although some cases are still pending, thus far the manufacturers and patients have largely prevailed. In the District of Delaware, Judge Leonard Stark explained that "Congress could have explicitly stated that drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies," but did not. *Astrazeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("*AstraZeneca I*"). In the District of Columbia, Judge Friedrich held that "[n]either the 'Shall Offer' provision nor any other Section 340B contains . . . clear language that forbids drug manufacturers from imposing *any* additional conditions—no matter how minor—on covered entities that purchase drugs at 340B discount prices." *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *7 (D.D.C. Nov. 5, 2021).

On January 30, 2023, the Third Circuit issued a unanimous decision in manufacturers' favor. The court of appeals explained that Congress intentionally "chose not to" impose delivery-related obligations on manufacturers, noting that the federal 340B statute's plain text suggests that Congress intended "one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *See Sanofi Aventis*, 58 F.4th 696 at 704. The Third Circuit held that manufacturers' policies do not prevent covered entities from participating in the 340B

[5] *See, e.g., Sanofi Aventis U.S. LLC v. U.S. Dept. of Health & Human Servs.,* 58 F.4th 696 (3d Cir. 2023) (addressing cases filed by three manufacturers); *Novartis Pharmaceuticals Corp. v. Johnson et al*., No. 21-5299 (D.C. Cir.) (pending) (considering cases filed by two manufacturers); *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs., et al.*, No. 21-3405 (7th Cir.) (pending).

program or from entering into contractual relationships with commercial pharmacies. Covered entities "can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy." *Id*. at 703. The Third Circuit recognized that manufacturers may address program abuses by imposing restrictions on when they will transfer discounted drugs to commercial pharmacies. *Id.* at 705.

Louisiana Attempts To Undo The Third Circuit Ruling

This litigation concerns Act 358, Louisiana's attempt to use state law to change how the 340B program works—taking the same position that was rejected by the Third Circuit. Louisiana's Attorney General filed amicus briefs on behalf of Louisiana in the Third Circuit, expressing disapproval of the manufacturers' policies. *See* Press Release, Attorney General Landry, *Defending Affordable Drug Prices, Attorney General Jeff Landry Joins Bipartisan, Nationwide Coalition* (May 16, 2022), https://www.houmatimes.com/news/ag-jeff-landry-joins-bipartisan-nationwide-coalition-to-defend-affordable-drug-prices/. On March 31, 2023, only two months after the Third Circuit's decision upholding the manufacturers' policies, Act 358 was introduced in the Louisiana House of Representatives. On June 12, 2023, the Louisiana Legislature enacted Act 358 into law as "The Defending Affordable Prescription Drug Costs Act." La. Stat. Ann. § 40:2881, *et seq.*

Act 358 regulates manufacturers' compliance with the federal 340B program and, by its terms, could not exist absent the 340B program, which it refers to repeatedly. Section 2882 defines the terms "340B drug" and "340B entity" by referencing 42 U.S.C. § 256b, the 340B statute. *See* La. Stat. Ann. § 40:2882(1), (2) ("Definitions."). Act 358 also contains two provisions imposing obligations on pharmaceutical manufacturers under the federal program. Under the first, "[a] manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy

that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services." *Id.* § 40.2884(A). Under the second, "[a] manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity." *Id.* § 40.2884(B). And because Act 358's definitions of "340B drug" and "340B entity" explicitly refer to the federal 340B statute, the *only* individual drug units subject to regulation under these provisions are those purchased at the federal discounted price.

Act 358's text makes a violation an automatic violation of the Louisiana consumer-protection statute. *Id.* § 51:1401, *et seq.* A violation of Act 358 "subjects the violator to any and all actions, including investigative demands, remedies, and penalties provided for in the Unfair Trade Practices and Consumer Protection Law, except there shall be no right to bring private action pursuant to La. Stat. Ann. § 51:1409." *Id.* § 40:2885. "A violation occurs each time a prohibited act is committed." *Id.* Under Louisiana's Unfair Trade Practices and Consumer Law, the Attorney General and district attorneys under his supervision may seek "a civil penalty against any person found by the court to have engaged in any method, act, or practice in Louisiana declared to be unlawful" under the statute. *Id.* §§ 51:1407, 51:1417. The Attorney General and district attorneys may also seek injunctive relief for violations. *Id.* § 51:1407. In addition, courts may issue "such additional orders or render judgments against any party, as may be necessary to compensate any aggrieved person for any property . . . which may have been acquired from such person by means of any method, act, or practice declared unlawful" and these orders can include restitution, revocation of licenses or other authority to conduct business, appointment of a receiver, dissolution of Louisiana corporate entities, and suspension or termination of foreign corporate entities' right to do business in Louisiana. *Id.* § 51:1408.

Act 358 purports to limit its scope, stating that "[n]othing in this Chapter is to be construed or applied to be less restrictive than federal law for a person or entity regulated by this Chapter." *Id.* § 40:2886. It further states that "[n]othing in this Chapter is to be construed or applied to be in conflict with any of the following: (1) Applicable federal law and related regulations [or] (2) Other laws of this state if the state law is compatible with applicable federal law." *Id.*

This Lawsuit

AbbVie filed suit against the Attorney General challenging the constitutionality of Act 358. AbbVie has raised four claims for relief: *First*, Act 358 violates the Supremacy Clause, U.S. Const. art. VI, cl. 2, because the federal 340B program preempts the Louisiana law. Am. Compl. ¶¶ 101–06 (field preemption), 107–10 (conflict preemption). *Second*, Act 358 effects an unconstitutional taking of private property. Act 358 "appropriates AbbVie's property rights in its drugs for private benefit of for-profit, commercial pharmacies" which effectuates "an impermissible per se violation of the Constitution's Takings and Due Process Clauses." *Id.* ¶¶ 111–16 (citing U.S. Const. amends. V, XIV). The statute also "effectuates a partial regulatory taking" given its "purported requirement that manufacturers transfer their drugs to commercial pharmacies [which] . . . deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties." *Id.* ¶¶ 117–19 (citing *Penn Central Transp. Corp. v. New York City*, 438 U.S. 104, 124 (1978)). *Third*, to the extent that the federal 340B program does not preempt Act 358, the Louisiana statute violates the takings clause under the Louisiana Constitution. *Id.* ¶¶ 120–26. *Fourth*, Act 358 is unconstitutionally vague in violation of the Fourteenth Amendment's Due Process Clause, U.S. Const. ament. XIV. *Id.* ¶¶ 127–33. For those claims, AbbVie requested declaratory and injunctive relief. *Id.* ¶¶ 94–100.

AbbVie now moves for summary judgment.

STANDARD OF REVIEW

This Court should grant summary judgment if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a).

ARGUMENT

Louisiana's attempt to force manufacturers to transfer their drugs at discounted prices to entities that, under the federal program, have no entitlement to access those drugs is preempted as a matter of federal law. If it is not preempted, the Louisiana statute effectuates an unconstitutional taking. The statute is also unconstitutionally vague.

I. ACT 358 IS PREEMPTED.

Act 358 is preempted by federal law. Under the Constitution's Supremacy Clause, federal statutes are "the supreme law of the Land … any Thing in the Constitution or Laws of any State to the contrary notwithstanding." U.S. Const., art. VI. Act 358 is preempted by federal law in two ways: First, it impermissibly intrudes on a field of federal regulation created and occupied by Congress. Second, it conflicts with Congress's objectives in the 340B program by attempting to enforce an alternative interpretation of the 340B statute rejected by the federal courts.

A. Act 358 Is Preempted Because It Intrudes On An Exclusively Federal Field.

Because the supremacy of federal law is "essential to the existence and preservation of the government," the Supreme Court has recognized that "[C]ongress should be able to exercise its constitutional powers, at its own discretion, without being subject to the control of state legislation." *M'Culloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 330 (1819). For that reason, the Supreme Court has held that state law is preempted whenever (1) Congress's "framework of regulation [is] 'so pervasive'" that Congress has "left no room for the States to supplement it," or (2) there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387, 399

(2012); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Field preemption is likely when a state law "diminish[es] the [federal government]'s control over enforcement and detract[s] from the integrated scheme of regulation created by Congress." *Arizona*, 567 U.S. at 402 (internal quotations and citations omitted). Because Act 358 intrudes on a comprehensive federal scheme, it runs afoul of the Supremacy Clause.

1. Section 340B Erects A Comprehensive Scheme Governing An Exclusively Federal Program.

When Congress creates a statutory framework entailing "single integrated and all-embracing system," it preempts the field. *See id.* at 400–01; *Hines v. Davidowitz*, 312 U.S. 52, 74 (1941); *see also American Ins. Ass'n v. Garamendi*, 539 U.S. 396, 419 n.11 (2003) (*Hines* is a field preemption case). The 340B statute does just that.

Congress created the federal 340B program, rendering it a purely federal creature. There is no pre-existing state common-law right to access manufacturers' drugs at deeply discounted 340B prices, and the rights granted and obligations created by the 340B statute—which apply solely as a condition of participating in the federal 340B program—do not exist except as provided by Congress. Indeed, 340B is doubly federal, as participating in the 340B program is a condition of participation in *other* federal drug programs, Medicare and Medicaid. 42 U.S.C. § 256b(a). There is no room for the states to interfere with the uniform federal scheme, created and governed by federal law, or to impose additional state-law obligations as conditions of participation in federal healthcare programs.

The 340B program's inflexible terms are, by statutory command, repeated and embodied in federal contracts between manufacturers and the Secretary of HHS. *Astra*, 563 U.S. at 118 ("The form agreements, composed by HHS, contain no negotiable terms."); *id.* ("The statutory and contractual obligations, in short, are one and the same."). If manufacturers fail to provide

discounted drugs to covered entities as that contract requires, they could lose access to federal Medicare or Medicaid programs. 42 U.S.C. § 1396r-8. The Supreme Court has thus recognized that 340B and the Medicaid Drug Rebate Program are "interdependent" programs, and that "[a]n adjudication of rights under one program must" therefore "proceed with an eye towards any implications for the other." *Astra*, 563 U.S. at 114, 120. Maintaining a harmonious balance between the two programs is a dominant federal interest. *See Witty v. Delta Air Lines, Inc.*, 366 F.3d 380, 385 (5th Cir. 2004) (concluding that federal regulatory requirements under the Federal Aviation Act for passenger safety warnings were exclusive because the federal statute "require[d] a delicate balance between safety and efficiency" and the "interdependence of these factors requires a uniform and exclusive system of federal regulation if the congressional objectives underlying the [federal statute] are to be fulfilled" (quoting *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 638-39 (1973))); *see also Leslie Miller, Inc. v. Arkansas*, 352 U.S. 187 (1956) (holding that state laws seeking to impose licensing requirements on federal contractors preempted by federal law).

Congress also dictated all of the 340B program's substantive rules and expressly limited which entities are entitled to participate in and benefit from the federal program. Congress enumerated fifteen types of organizations that can qualify as "covered entities" entitled to access drugs at the discounted 340B price. 42 U.SC. § 256b(a)(4). It created a set of rules those entities must abide by, including a prohibition on duplicate discounts or rebates ("duplicate discounting"), and reselling drugs to anyone other than 340B "patients" ("diversion"). *See id.* § 256b(a)(5)(B). It instructed manufacturers that they "shall . . . offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other

purchaser at any price." *Id.* § 256b(a)(1). And the meaning of the "shall … offer" provision is a question a federal law. *See Sanofi*, 58 F.4th at 703–06.

The realm of "contract pharmacies" is no different. Indeed, the very *existence* of 340B contract pharmacies depends on the federal 340B program. These types of contract pharmacies are commercial pharmacies that contract with 340B covered entities to dispense 340B drugs at federally discounted prices. And they access 340B discounted drugs through a "replenishment" model that does not exist outside the context of the federal 340B program. If Congress repealed the 340B statute tomorrow, the term "340B contract pharmacy" would cease to have any meaning.

Congress also established a comprehensive, carefully balanced, and exclusive remedial scheme. The 340B statute establishes an exclusive regime for adjudicating disputes between manufacturers and covered entities through audits and a federal Administrative Dispute Resolution ("ADR") process conducted by a specially appointed federal tribunal. 42 U.S.C. § 256b(d)(1)(B)(v), (d)(3); *Astra*, 563 U.S. at 118. ADR proceedings cover claims that covered entities that have been "overcharged" by manufacturers that failed to offer them access to their drugs at the 340B ceiling price when they were supposed to. 42 U.S.C. § 256b(d)(3)(A). Congress, moreover, instructed the HHS Secretary to develop certain program improvements to ensure compliance by covered entities and to prevent diversion to non-patients and duplicate discounts. Congress also granted HRSA authority to audit covered entities' financial records, impose civil monetary sanctions, and, when necessary, remove a covered entity from participating in the program. *Id.* It gave HRSA specific tools to increase the integrity of the federal program, including by allowing the agency to verify the accuracy of ceiling prices, establishing procedures to issue refunds to covered entities in the event there is an overcharge. Failure to comply with the 340B program's statutory requirements may result in termination of the PPA and the

manufacturer's ability to participate in Medicaid, federal enforcement actions, and potential imposition of large civil penalties. *Id.* § 256b(a)(5)(D), (d)(1)(B)(vi), (d)(2)(B)(v), (d)(3)(A). The statute also provides the Secretary of HHS, through the HHS sub-division, HRSA, with exclusive enforcement authority. *Id.* § 256b(a)(5)(C)–(D), (d)(1)(B)(v), (d)(3).

In short, the 340B program was designed as a "'harmonious whole'" and does not leave any room for states to supplement or interfere with the carefully designed 340B program or change the requirements for participation in that federal program. *Arizona*, 567 U.S. at 401 (quoting *Hines,* 312 U.S. at 72); *see also Astra*, 563 U.S. at 120. The federal 340B statute therefore preempts any state law attempting to enter that field.

2. Act 358 Impermissibly Intrudes On A Congressionally Occupied Field And Conflicts With The Supreme Court's Decision in *Astra*.

The oldest principle of federal preemption law, long preexisting its modern doctrinal categories, is that States may not regulate what Congress has made. *See M'Culloch*, 17 U.S. (4 Wheat.) 316 (1819). To allow Maryland to tax the Bank of the United States, for example, would "subject every important measure of the national government to the revision and control of the state legislatures." *Id.* at 327–29. As Chief Justice Marshall explained, "if the law of congress, establishing the bank, be a constitutional act, it must have its full and complete effects. Its operation cannot be either defeated or impeded by acts of state legislation." *Id.* at 330.

Act 358 violates that basic principle and impermissibly intrudes on the 340B program's exclusively federal field. The plain text of Act 358 confirms that conclusion. Act 358 refers to the federal 340B program thirty-eight times in its four and a half pages of text. Indeed, Act 358 defines the terms "340B drug" and "340B entity" by direct reference to the federal statute. *See* La. Stat. Ann. § 40:2882(1), (2). Act 358 also regulates certain "discriminatory actions," but only in reference to the reimbursement of 340B entities. *Id.* at §§ 40:2883-40:2884. The Act's purpose

is to augment, and modify, manufacturers' obligations *under the federal 340B* program. States have no power to regulate federal spending programs in that fashion. *See United States v. Certain Land Situated in City of Detroit, Wayne Cnty., Mich.*, 43 F. Supp. 2d 762, 772 (E.D. Mich. 1999) ("the problem with Intervenors' argument is that this matter involves a Federal project which is being funded with Federal funds. The State cannot constitutionally limit what the Federal government does to fund its projects."). Act 358 is thus preempted.

Indeed, Act 358 is aimed at the heart of the federally occupied 340B field: what below-market sale offers manufacturers must make and which entities are entitled to access manufacturers' drugs at the federally discounted 340B price. As the Third Circuit has confirmed, to participate in Medicare and Medicaid, the 340B statute requires manufacturers to offer drugs to covered entities at discounted prices, but not to transfer their discounted drugs to contract pharmacies. *Sanofi*, 58 F.4th at 706. Act 358, however, purports to require manufacturers to also "offer" 340B-discounted drugs to contract pharmacies, La. Stat. Ann. §§ 40:2882(2), 40:2884(A), thereby altering the substance of Congress's choice.

The Attorney General's Answer to AbbVie's complaint emphatically and repeatedly confirms that Act 358's objective is to reverse the Third Circuit's decision and expand manufacturers' 340B obligations. No fewer than 15 times, the Answer says that Louisiana's complaint with manufacturers' 340B contract-pharmacy policies is that they "result[] in Plaintiffs *overcharging covered entities for 340B drugs.*" Answer ¶ 66 (emphasis added).[6] But whether

[6] *See also* Answer ¶ 7 (noting a supposed "sharp increase in overcharges to covered entities following the implementation of such policies"); *id.* ¶ 62 ("Answering further, Members of Congress have asked HSRA to institute enforcement actions against pharmaceutical manufacturers ... that unilaterally impose policies that *result in overcharges to covered entities for 340B drugs.*"); *id.* ¶ 64 ("Defendant admits that Plaintiffs have refused to deliver 340B drugs to contract pharmacies unless covered entities *pay more than the mandated 340B price* . . . Defendant denies that Plaintiffs have any lawful right *to charge covered entities more for 340B drugs than required under their PPA* ...."); *id.* ¶ 65 ("Plaintiffs have transmitted correspondence to covered entities stating that Plaintiffs will not deliver 340B drugs purchased by a covered entity to contract

covered entities have been "overcharge[ed] … for 340B drugs" is exclusively a question of federal law about the proper interpretation of the 340B statute. That is the precise argument HHS advanced, and lost, in the Third Circuit: *Sanofi* arose because HHS sent letters to drug manufacturers alleging that their 340B contract pharmacy policies "were unlawful and ordered them to rescind those policies and reimburse covered entities *for any overcharges*." *Sanofi*, 58 F.4th at 701 (emphasis added). That determination was vacated because, under the proper interpretation of Section 340B, there *were no* overcharges: Because manufacturers' interpretation of the statute was correct, they were not required to offer to deliver drugs "to an unlimited number of contract pharmacies" at the ceiling price, *id.* at 704, so they committed no overcharges by refusing to do so. By contrast, the Attorney General expressly admits that "Act 358 … simply requires manufacturers to offer drugs to an unlimited number of contract pharmacies"—*i.e.*, exactly what the Third Circuit says they need not do. Cross-Motion for Summ. J., *AstraZeneca Pharms. LP v. Landry*, No. 6:23-cv-01042-RRS-CBW (W.D. La. Dec. 15, 2023) (ECF No. 43) ("Att'y Gen. AZ Br."), at 21

Act 358 thus reflects Louisiana's dissatisfaction with a federal court's reading of federal law. The statute seeks to replace Congress's judgment with the Louisiana legislature's own policy preferences. Act 358 would allow the Attorney General to seek injunctions and potential monetary

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pharmacies *unless the covered entity pays more than the mandated 340B price* ...."); *id.* ¶ 67 ("[R]egardless of any 'commitments' Plaintiffs have made, their policies regarding contact pharmacies have *resulted in overcharging covered entities for 340B drugs*"); *id.* ¶ 71 ("[T]he federal government sent Plaintiffs correspondence stating that AbbVie's internal policies relating to contract pharmacies had r*esulted in the manufacturer overcharging covered entities for 340B drugs in direct violation of the 340B statute.*" (internal citations omitted)); *id.* ¶ 72 (same); *id.* at ¶ 74 (same); *id.* at ¶ 76 (same); *id*. ¶ 98 ("Plaintiffs do not have a constitutional right to adopt internal policies that result in *overcharging entities for 340B drugs* ...."); *id.* ¶ 99 ("the specific policies implemented by Plaintiffs have resulted in *overcharging covered entities for 340B drugs in direct violation of the federal 340B statute*."); *id*. ¶ 100 (same); *id.* ¶ 131 ("Answering further, the Third Circuit's decision in Sanofi Aventis did not consider Plaintiffs' policies, nor did it find that policies that *result in overcharging covered entities for 340B drugs* are lawful under the federal 340B statute."). (all emphasis added).

penalties of up to $5,000 per violation to force manufacturers to conform to Louisiana's view of how 340B should operate. La. Stat. Ann. § 51:1407(B), *id.* § 52:1416.

The Attorney General's Answer also demonstrates that Act 358 is aimed at interfering with the exclusive authority of the federal ADR tribunals. The federal ADR process provides the exclusive cause of action and remedy for covered entities that believe a manufacturer has failed to provide drugs at the 340B price. Federal tribunals have explicit and exclusive authority to adjudicate "claims by covered entities that they have been overcharged for drugs purchased under this section." 42 U.S.C. § 256b(d)(3)(A). There is "no such thing as a state-law claim" to enforce the federal 340B law. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 11 (2003). Again, the Attorney General repeatedly and openly admits Act 358 treats as "overcharges" manufacturers' refusal to cooperate with an unlimited number of contract-pharmacy arrangements and seeks to remedy them through penalties. *See supra* n.6. Yet Congress allocated HRSA alone the power to regulate pricing of 340B drugs. Louisiana's attempt to regulate and enforce federal law is therefore barred by the field-preemption doctrine. *See Forest Park II v. Hadley,* 336 F.3d 724, 732 (8th Cir. 2003) (noting that "state statutes may not interfere with the implementation of a federal program by a federal agency").

The Supreme Court's decision in *Astra* strongly supports that conclusion. In *Astra*, Santa Clara County Hospital, a 340B covered entity, brought suit against Astra USA Inc. and several other pharmaceutical manufacturers seeking damages stemming from alleged "overcharges" of 340B drugs (*i.e.*, that Santa Clara had paid above the ceiling price set by the PPA). *Astra*, 563 U.S. at 113, 121–22 (noting that Congress created an adjudicative framework "for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements'"). A unanimous Supreme Court repudiated that suit. It explained that, in adopting 340B, Congress

granted the Secretary of HHS sole control of administration of the 340B program. *Id.* at 113. The Court concluded that Congress intended to "centralize" enforcement given Congress's "direct[ion to] HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers." *Id.* at 121. Given that direction, the Court concluded that allowing civil suits as an additional mechanism of enforcement would be "incompatible with the statutory regime." *Id.* at 113. "Far from assisting HHS, suits by 340B entities would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 120. As the Court put it, "Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework *the proper remedy* for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements.'" *Id.* at 122–23 (emphasis added).

Astra's analysis shows that alternative enforcement mechanisms for alleged overcharges intrude on the core of a federally occupied field. The *Astra* Court held that because Congress intended to "centralize[] enforcement in the government," "spreading the enforcement burden" beyond the ADR process would frustrate Congress's purpose. *Id.* at 119; *see also* Brief of United States as *Amicus Curiae*, *Astra*, No. 09-1273 (S. Ct. Nov. 2010) ("U.S. Brief") at 32 (agreeing). The Court concluded that permitting extra-agency enforcement of 340B compliance "would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 562 U.S. at 120; U.S. Brief at 33–34. The Court worried that "[r]ecognizing the County's right to proceed in court could spawn a multitude of dispersed and uncoordinated lawsuits by 340B entities," and that because HHS would be "unable to hold the control rein, the risk of conflicting adjudicating would be substantial." *Astra*, 562 U.S. at 120.

That reasoning mirrors the Court's field preemption cases. In *Arizona*, for example, the Court held that the statutory framework governing federal immigration was so comprehensive that Congress intended to preempt the field. 567 U.S. at 403-04. Congress left no room for states to regulate national immigration because it specified which categories of immigrants may be admitted to the United States, created federal offenses for failure to comply with the federal scheme, required registrations for immigrants once they met the necessary qualifications, and provided powers to States to deny noncitizens a range of public benefits. *Id.* at 395–96. The Court reasoned that the immigration laws "provide[d] a full set of standards governing alien registration, including the punishment for noncompliance" and, therefore, any state attempts to regulate immigration law were unconstitutional where Congress intended to occupy the field. *See id.* at 401–04; *see also Howard v. Uniroyal, Inc.*, 719 F.2d 1552, 1562 (11th Cir. 1983) (holding in another context that state law was preempted because remedy was provided under federal dispute resolution process and state enforcement would therefore frustrate federal administrative scheme).

The same logic requires preemption here. Because 340B is comprehensive, it not only excludes private lawsuits, it also creates an exclusive field of federal authority. *See, e.g.*, *Arizona*, 567 U.S. at 402-03 (concluding that "state framework of sanctions creates a conflict with the plan Congress put in place" "[e]ven where federal authorities believe prosecution is appropriate"); *Wis. Dep't of Indus., Labor & Human Rels. v. Gould Inc.*, 475 U.S. 282, 288–89 (1986) ("Each additional [State] statute incrementally diminishes the [federal government]'s control over enforcement" and "detracts from the 'integrated scheme of regulation' created by Congress."). No room remains for state law to change the requirements of the federal 340B program.

3. Congress Left No Gap In 340B For States To Fill.

To the extent the Attorney General claims Act 358 merely fills in some "gap" Congress left in 340B, that is wrong. The 340B program is a complete whole. Allowing states to regulate

who can participate in the 340B program and gain access to manufacturers' drugs at 340B discounted prices would fundamentally change the requirements for participation in the federal program, making them more onerous and costly than Congress intended.

There are times when federal programs, like Medicare and Medicaid, expressly call for State law. *See, e.g.*, 42 U.S.C § 1396a (State plans for medical assistance); § 1396c (Operation of State plans); § 1396g (State programs for licensing of administrators of nursing homes); § 1396h (State false claims act requirements for increased State share of recoveries); § 1396n (Compliance with State plan and payment provisions); § 1396o-1 (State option for alternative premiums and cost sharing); § 1396u-7 (State flexibility in benefit packages); § 1396w-3 (Enrollment simplification and coordination with State health insurance exchanges); § 1396w-4 (State option to provide coordinated care through a health home for individuals with chronic conditions); § 1396w-4a (State option to provide coordinated care through a health home for children with medically complex conditions); § 1396w-6 (State option to provide qualifying community-based mobile crisis intervention services). Tellingly, 340B does not.

Nor did Congress leave it to States to decide whether contract pharmacies have a proper role in the 340B program in the guise of "acquisition and delivery." Att'y Gen. AZ Brief Br. at 12. Congress has authorized contract pharmacy participation in other statutory programs but not in this one. *Sanofi*, 58 F.4th at 704–05 (explaining that Congress provided for "contract pharmacies" in another statutory provision, but not in 340B). Congress has also specified when covered entities are permitted to "enter into contracts" with other entities for "the distribution of covered outpatient drugs," but that provision does not apply here. 42 U.S.C. § 256b(a)(8) (discussing distribution permitted in the limited context of a federal prime vendor program).

In *Sanofi*, the Third Circuit explained that Congress did not require manufacturers to deliver 340B discounted drugs to contract pharmacies. *Sanofi*, 58 F.4th at 704 (explaining that the federal 340B statute's plain text suggests that Congress intended "one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies."). That is not a "gap" for states to fill. *Puerto Rico Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988) ("Where a comprehensive federal scheme intentionally leaves a portion of the regulated field without controls, *then* the pre-emptive inference can be drawn—not from federal inaction alone, but from inaction joined with action."); *Hines*, 312 U.S. at 59-61, 72-74. To the contrary, by requiring manufacturers to offer drugs to covered entities, but not to participate in unlimited contract-pharmacy arrangements, Congress set the *conditions* of manufacturers' participation in Medicare and Medicaid programs. States cannot change Congress's conditions by calling it "gap filling."

As for "acquisition and delivery," that is a red herring. There is no dispute that pharmacies across Louisiana are able to acquire AbbVie's and other manufacturer's drugs and can have those drugs delivered to them through ordinary distribution channels. The entire point of Act 358 is to provide pharmacies access to manufacturers' drugs *at the federal 340B price*. As the Attorney General has repeatedly admitted, in his briefs and in his Answer, Act 358 is aimed at requiring "manufacturers to offer drugs to an unlimited number of contract pharmacies," Att'y Gen. AZ Br. at 21, so that covered entities will earn more "revenue," *id*. at 5, and not be "overcharged," Answer ¶ 66. But as explained above, *Astra* held that HRSA has the exclusive authority to regulate and remediate the 340B statute, which includes pricing. Act 358 is thus specifically aimed at expanding the federal requirements imposed on manufacturers by changing which entities are entitled to access manufacturers drugs at federal 340B discounted prices.

In fact, the statutory scheme here is so pervasively federal that it is akin to situations where courts have held that state regulation is *completely* preempted (a standard that AbbVie need not meet to prevail). Consider the National Bank Act, which preempts the field of state regulation relating to the interest rates that any national bank may charge. Because the federal statute imposes substantive limits on the rates of interest that national banks may charge and also sets forth the exclusive remedies available against a national bank alleged to have charged excessive interest—*i.e.*, overcharges—the Court held that federal law completely defines what counts as usury by a national bank and leaves no power to supplement the federal scheme by state legislation. *See Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 10 (2003). As the Court explained, "[u]niform rules limiting the liability of national banks and prescribing exclusive remedies for their overcharges are an integral part of the federal banking system" that "supersede[s]" the "substantive" and "remedial" provisions of state law and creates a "federal remedy for overcharges that is exclusive." *Id*. at 10–11. Accordingly, even though national banks remain "subject to state laws of general application in their daily business," the states have no authority to regulate interest rates or to enforce penalties for alleged overcharges. *See Watters v. Wachovia Bank, N.A.*, 550 U.S. 1, 11 (2007). The same is true here.

In any event, Congress could not constitutionally leave to the States the discretion to enact laws like Act 358. As explained below, when *Congress* requires manufacturers to provide their drugs to other private parties at below-market prices, it (at least arguably) pays for them by offering Medicare and Medicaid participation in return. A state law commanding such a transfer, not as a condition of voluntary participation in some benefit program, is an unconstitutional taking—a bare forced transfer of property from one private party to another. If the only supposed "gap" the Attorney General can point to leaves only unconstitutional action unregulated, then Congress left

no gap at all. *See United States ex rel. Attorney General v. Delaware & Hudson Co.*, 213 U.S. 366, 407 (1909) (canon of constitutional avoidance).

B. Act 358 Is Preempted Because It Conflicts With Federal Law.

Act 358 is also preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000). That is so for three reasons.

First, Act 358 conflicts with Congress's design of the 340B program. As the Third Circuit explained in *Sanofi*, Congress "intentionally" omitted any obligation on manufacturers to transfer their drugs at 340B discounted prices to contract pharmacies. 58 F.4th at 704. That is a key congressional choice, for requiring manufacturers to transfer their drugs at discounted prices to unlimited numbers of contract-pharmacy arrangements transforms Congress's program from an *adjunct* to Medicare and Medicaid to something *bigger* than Medicaid. Act 358 seeks to undo that choice, by forcing manufacturers to deliver "a 340B drug to[] a pharmacy that is under a contract with a 340B entity." La. Stat. Ann. § 40:2884(A). As the Attorney General has admitted, in the State's view "Act 358 . . . simply requires manufacturers to offer drugs to an unlimited number of contract pharmacies," Att'y Gen. AZ Br. at 21, precisely what the Third Circuit has held 340B statute *does not* require.

By the State's own admission, then, Act 358 effectively abolishes a key limitation Congress imposed on manufacturers' 340B obligations. That frustrates Congress's objectives, for "textual limitations upon a law's scope are no less a part of its 'purpose' than its substantive authorizations." *Rapanos v. United States*, 547 U.S. 715, 752 (2006); *Director, Office of Workers' Compensation Progs. v. Newport News Shipbuilding & Dry Dock Co.*, 514 U. S. 122, 135–36 (1995) (same). Congress can decide to ask manufacturers for X amount of money to participate in Medicare and Medicaid, but not to ask for *more*. Yet by requiring broad dissemination of 340B-

priced drugs to contract pharmacies, Act 358 is designed to allow "covered entities" to "squeeze [more] revenue out of" the 340B program—even though Congress did not intend to "help [covered entities] maximize their 340B profits." *Sanofi*, 58 F.4th at 704. Again, the Attorney General complains that manufacturer's policies "deprive[] Covered Entities of the revenue . . . Congress intended in enacting the 340B program." Att'y Gen. AZ Br. at 5. That position is squarely contrary to *Sanofi*—but crisply illustrates that Louisiana's objective here is to impose a different interpretation *of federal law* than the Third Circuit adopted.

Second, Act 358 contravenes Congress's decision to vest exclusive authority for enforcing the 340B statute in HRSA and its ADR tribunals. As the Court explained in *Arizona*, a state law that unilaterally authorizes state officials to enforce a federal program can violate Congress' goal to leave enforcement to the federal government. *Arizona*, 567 U.S. at 409. In that case, because Congress instituted a specific enforcement system, a state law was preempted because it allowed state officials to "engage in . . . enforcement activities as a general matter" preventing Congress from enforcing a single system." *Id.* at 410. That is because "conflict is imminent" when "two separate remedies are brought to bear on the same activity." *Crosby*, 530 U.S. at 380 ("[T]he inconsistency of sanctions here undermines the congressional calibration of force."); *Villas at Parkside Partners v. City of Farmers Branch, Tex.*, 726 F.3d 524, 530 (5th Cir. 2013) (explaining that local prohibition on renting to non-citizens was contrary to law because it obstructs the goal of bringing potentially removable non-citizens to the attention of the federal authorities).

Here, federal law prescribes a specific and exclusively federal enforcement regime for 340B. The Supreme Court has recognized that "Congress can act so unequivocally as to make clear that it intends no regulation except its own" and its decision to "regulat[e] by one agency" is an example of unequivocal intent. *See Santa Fe Elevator Corp.*, 331 U.S. at 236. This is one such

occasion. As explained above, the 340B statute vests HRSA with carefully balanced and comprehensive enforcement tools. *See* § I.A.1, *supra.* ADR tribunals, for example, adjudicate claims that covered entities have been "overcharged" by manufacturers that failed to afford them the 340B ceiling price when they were supposed to. 42 U.S.C. § 256b(d)(3)(A) ("[T]he Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section.").

Act 358 conflicts with these provisions by purporting to set up an additional enforcement scheme over which HRSA has no control. A violation of Act 358 is also a violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Stat. Ann. 51:1401 *et seq*., granting the Attorney General the ability to seek "a civil penalty," *id.* §§ 51:1407, 51:1417, as well as injunctive relief, *id.* § 51:1407. But the 340B federal program already vests such enforcement authority—and the decision making power about whether to exercise it—in HRSA. *See* 42 U.S.C. § 256b; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 342-43, 349-50 (2001) (where agency had "a variety of enforcement options that allow it to make a measured response," permitting state tort claims would "inevitably conflict with the [agency]'s responsibility to police fraud consistently with [its] judgment and objectives").

Act 358 would also allow state enforcement actions when HRSA itself could *not* act. Congress imbued HHS with the power to levy monetary penalties in only certain circumstances and through a certain procedure. 42 U.S.C. § 256b(d)(1)(B) (requiring HHS "inquir[e]" into "pricing discrepancies," have manufacturers take "corrective action," and utilize audits). Act 358 contains no such process. Paradoxically, this means the State could impose a monetary penalty where HRSA—Congress's chosen enforcement body—would be prohibited from doing so.

Granting a state the right to impose a right or remedy "withheld from [a federal agency] only accentuates the danger of conflict." *San Diego Bldg. Trades Council, Millmen's Union, Lc. 2020 v. Garmon*, 359 U.S. 236, 247 (1959); *Villas at Parkside*, 726 F.3d at 529-30.

Astra also illustrates why Act 358 conflicts with the federal scheme. *Astra* held that HRSA's remedial and enforcement authorities in the 340B area were intended to be exclusive *and therefore foreclosed* any private cause of action to enforce the 340B statute through civil litigation. *Astra*, 563 U.S. at 117 ("Congress vested authority to oversee compliance with the 340B program in HHS and assigned no auxiliary enforcement role to covered entities."). The *Astra* Court concluded that allowing decentralized 340B enforcement through litigation posed "substantial" risk to the federal scheme because "potentially thousands of covered entities [would be] permitted to bring suits alleging errors in manufactures' price calculations." *Id.* at 114. A state law purporting to authorize 340B enforcement actions or litigation outside of the channels Congress established has the same effect: It frustrates Congress's goal of having a single, federal enforcement authority for 340B by allowing the Louisiana Attorney General to perform the same function.

Indeed, the Attorney General's Answer to AbbVie's complaint straightforwardly admits Act 358 is designed to address "overcharges," *i.e.*, alleged violations of Section 340B's substantive requirements. Answer ¶¶ 14, 33, 116. As explained above, the Attorney General complains more than 15 times throughout his Answer that manufacturers' implementation of 340B contract pharmacy policies "result[] in Plaintiffs *overcharging covered entities for 340B drugs.*" *E.g.*, Answer ¶ 66. That is precisely the kind of claim *Astra* holds can be resolved only through HRSA's procedures. In *Astra* itself, the lawsuit rejected by the Supreme Court, filed by an "operator of several 340B entities," alleged that nine manufacturers "were overcharging 340B entities in

violation of the PPAs." *Astra*, 563 U.S. at 116. What the Supreme Court said made clear that it was Congress's decision "to make the new [ADR] adjudicative framework *the proper remedy* for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements.'" *Id.* at 114 (quoting 42 U.S.C. § 256b(d)(1)(A)) (emphasis added). The Louisiana legislature is not entitled to decide that lawsuits in Louisiana courts brought by its Attorney General would be a better remedy.

* * *

It should be obvious that it cannot force manufacturers to transfer drugs to a preferred political constituency, such as contract pharmacies, just because it disagrees with the requirements of federal law and the outcome of federal litigation in which it participated. Act 358 is preempted twice over. It intrudes into a field occupied by Congress; and then acts to frustrate the choices Congress made when it set up that field in the first place. The statute should not be permitted to stand.

II. ACT 358 EFFECTS AN UNCONSTITUTIONAL TAKING.

If not preempted, Act 358 effects an unconstitutional taking of private property. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." Louisiana's Constitution contains similar prohibitions: "Property shall not be taken or damaged by the state or its political subdivisions except for public purposes and with just compensation . . . ." La. Const. art. I, § 4(B)(1). "[U]nder both Constitutions, any expropriation must be for a *public purpose* and provide *just compensation*." *St. Bernard Port, Harbor & Terminal Dist. v. Violet Dock Port, Inc., LLC*, 239 So. 3d 243, 250 (La. 2018) (emphasis added) (internal quotations omitted).

A. Act 358 Mandates An Unconstitutional Private Wealth Transfer.

The drugs AbbVie produces are its property protected by the Takings Clause. That they are chattels and not land does not matter. Personal property, like real estate, is protected from illegal taking by the government. *Horne v. Dep't of Agric.*, 576 U.S. 530, 358 (2015) ("The Government has a categorical duty to pay just compensation when it takes your car, just as when it takes your home."). Our "law has most carefully protected the ownership of personal property." *Shaw v. Merchants' Nat'l Bank*, 101 U.S. 557, 565–66 (1879). As the Supreme Court has long recognized, the Takings Clause is "designed to bar the government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960); *Palazzolo v. Rhode Island*, 533 U.S. 606, 617–18 (2001). Legislatures must act by general law, not targeted measures aimed at imposing special burdens on the property rights of disfavored individuals or entities for the benefit of special interests.

The most basic principle of takings law is that legislatures may not take property from A and give it to B. The Supreme Court has made clear that "[a] purely private taking could not withstand the scrutiny of the public use requirement; it would serve no legitimate purpose of government and would thus be void." *Hawaii Hous. Auth. v. Midkiff*, 467 U.S. 229, 245 (1984). That has been the law in this country since the Founding. *See Calder*, 3 U.S. (3 Dall.) at 388 (1798) ("An act of the Legislature (for I cannot call it a law) contrary to the great first principles of the social compact, cannot be considered a rightful exercise of legislative authority . . . . A few instances will suffice to explain what I mean . . . . [A] law that takes property from A and gives it to B: It is against all reason and justice, for a people to entrust a Legislature with such powers; and, therefore, it cannot be presumed that they have done it."); *Wilkinson v. Leland*, 27 U.S. (2 Pet.) 627, 658 (1829) ("We know of no case, in which a legislative act to transfer the property of

A. to B. without his consent, has ever been held a constitutional exercise of legislative power in any state in the union. On the contrary, it has been constantly resisted as inconsistent with just principles, by every judicial tribunal in which it has been attempted to be enforced.").

Yet a private wealth transfer is precisely what Act 358 purports to accomplish: According to the Attorney General's own brief, "Act 358 … simply requires manufacturers to offer drugs to an unlimited number of contract pharmacies"—*i.e.*, private third parties—and "reroutes the flow of such drugs" to where the Louisiana legislature wants them to go. Att'y Gen. AZ Br. at 21; *see also* La. Stat. Ann. § 40:2884. That is a tacit confession of error. "[A] *physical* appropriation of property g[ives] rise to a *per se* taking, without regard to other factors." *Horne*, 576 U.S. at 360. AbbVie does not wish to offer to sell its drugs "to an unlimited number of contract pharmacies," Att'y Gen. AZ Br. at 21—much less to do so at prices as low as a penny, so that the pharmacy can resell them at full price and capture the *entire economic value* of the products AbbVie worked hard to make. Forcing it to do so is unconstitutional.

Nor can the Attorney General claim that this mandate makes no difference to AbbVie. Louisiana's complaint is that manufacturers who follow the Third Circuit's interpretation of the 340B statute are not giving away *enough* product at below market prices as low as a penny, such that covered entities are being deprived of "revenue." *See* Att'y Gen. AZ Br. at 5. In this context, "revenue" is a product of volume: The Attorney General means that covered entities would earn more revenue if AbbVie were forced to transfer *more* of its drugs at discounted prices to contract pharmacies, who can then sell them for full price and give back some of the resulting windfall profits to the covered entities whose entitlements they are borrowing. A state may not force such a transaction against the property owner's will.

Act 358 advances no "public use" recognized in American law. Both the Supreme Court and the Fifth Circuit have "increasingly intimated that history and tradition, including historical precedents, are of central importance when determining the meaning of the [federal] Takings Clause." *Baker v. City of McKinney*, 84 F.4th 378, 383 (5th Cir. 2023) (collecting cases). Founding-era states employed their eminent domain power to provide specific public facilities, such as roads, ferries, canals, and parks. *Kelo v. City of New London*, 545 U.S. 469, 512 (2005) (Thomas, J., dissenting). In the limited circumstances where the states put the taken property in possession of private parties, the recipients were common carriers— "quasi-public entities." *Id.* In more recent cases, the Supreme Court has sometimes approved *compensated* transfers of property to private parties for very specific and carefully circumscribed reasons: *e.g.*, to cure a blight, *Berman v. Parker*, 348 U.S. 26, 31 (1954), or to break a monopoly, *Midkiff*, 467 U.S. at 232–33 (approving Hawaii law addressing long-lasting land monopoly problem by enabling tenants to purchase the same land they leased). But even at its most permissive, the Supreme Court has consistently forbidden takings for the purpose of "conferring a private benefit on a particular private party" or "to benefit a particular class of identifiable individuals." *Kelo*, 545 U.S. at 477-78 (quotation marks omitted). Yet that is exactly what Act 358 does: it tries to secure for covered entities and contract pharmacies, not the public, the value of AbbVie's property. *See* Att'y Gen AZ Br. at 5. That is unconstitutional.

Act 358 fares even worse under Louisiana's own state constitution. Unlike its federal counterpart, the Louisiana Constitution specifies what uses are constitutionally permissible via a closed list. La. Const. art. I, § 4(B)(2). In every such authorized use, the taken property becomes either physically accessible to the public or is removed to prevent imminent harm writ large. As Louisiana Constitution § 4(B)(3) makes clear, the mere fact that a proposed taking may have an

"incidental benefit to the public" is not a relevant consideration. Because Act 358 serves no valid public purpose in Louisiana, it violates the state constitution.

B. Unlike the Federal Government, Louisiana Cannot Rely On Voluntary Exchange As A Defense To Takings.

Louisiana is differently situated from the federal government with respect to takings concerns. Because drug manufacturers nominally agree to participate in the 340B program as a condition of Medicare and Medicaid participation, 42 U.S.C. § 256b(a), the United States takes the position that they voluntarily agree to sales involving contract pharmacies. *See, e.g.*, Brief of United States, *Sanofi-Aventis*, No. 31-3167 at 45. That does not, of course, end the inquiry. The "government may require property owners to cede a right of access as a condition of receiving certain benefits" only if the condition has "an 'essential nexus' and 'rough proportionality'" to the underlying government interest prompting the exaction. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) (quoting *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994)). That is why the 340B statute must be interpreted for the benefit of poor and uninsured patients. Congress has no valid governmental interest in lining the pockets of covered entities and their contract pharmacies. *See Horne*, 576 U.S. at 366 (government may not "hold hostage" the right to do business in a particular industry only "to be ransomed by the waiver of constitutional protection."); *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (same).

Act 358 is not part of any such voluntary exchange to be analyzed under the unconstitutional conditions doctrine. As explained above, Act 358 is an attempt by Louisiana to engraft additional state-law requirements onto the federal statute. But there is no benefit that manufacturers receive in exchange for the burdens that Act 358 imposes. The statute is a mandate, backed by penalties. It commands one private party to deliver its property to another private party in exchange for no additional value or payment. That is unconstitutional. Period.

C. The Attorney General's Attempt To Defend Against the Takings Charge Is Unpersuasive.

Remarkably, in his Answer to AbbVie's complaint, the Attorney General defends Act 358 against the takings charge by claiming that none of the drugs the law affects are still AbbVie's property by the time the law touches them. *See* Answer ¶¶ 13, 33, 116. His argument runs like this: Louisiana law says that "[o]wnership is transferred between the parties as soon as there is agreement on the thing and the price is fixed, even though the thing sold is not yet delivered nor the price paid." La. Civ. Code Ann. art. 2456.[7] Although the Attorney General never clarifies or otherwise explains what he believes to be the contract that triggers the transfer a title, for the sake of argument we presume he means when covered entities place orders for 340B drugs. The Attorney General asserts that, once the covered entities place an order with AbbVie for drugs to be delivered to contract pharmacies at the ceiling price, they instantly obtain title to the discounted drugs, and so Act 358's regulation of delivery happens after AbbVie no longer has any property rights in the chattel. *See* Answer ¶¶116, 33.

As a legal matter, AbbVie has made no "agreement" to sell its drugs to covered entities under the unlimited contract-pharmacy terms those entities desire and Act 358 apparently demands. Louisiana contracts require the well-known elements of offer, acceptance, and consideration. *Jones v. James*, 101 So. 116, 117–18 (La. 1924) (a "contract must afford a complete expression of this meeting of the minds, and leave no material element unexpressed. Offer and assent must coincide, and the result must be a complete obligation."); *Read v. Willwoods Cmty.*, 165 So. 3d 883, 887 (La. 2015) ("A contract is formed by the consent of the parties established through offer and acceptance."). And here, the entire impetus for Act 358 is that AbbVie and other

[7] The Louisiana Attorney General cites La. Stat. Ann. Civ. Proc. Code § 2456 which applies to payment of a judgment. For purposes of argument, AbbVie construes the Attorney General to mean La. Civ. Code Ann. art 2456.

manufacturers will offer 340B drugs to covered entities (as federal law requires), but will transfer them to third party locations only on certain reasonable conditions the Louisiana legislature dislikes. AbbVie has not offered, and thus no one has accepted, *any* agreement to sell drugs to an unlimited number of contract pharmacies or to covered entities for delivery to such pharmacies. *See ECW Recoveries v. Woodward*, 196 So. 3d 122, 126 (La. Ct. App. 2016) ("[A]n acceptance not in accordance with the offer is deemed to be a counteroffer. Thus, unless the 'acceptance' is in accordance with the offer, it is not considered a valid acceptance for a valid contract."). What is more, if title were to transfer merely upon placement an order by a purchaser, then AbbVie—or indeed any seller—would be unable to confirm the identity of the purchaser, let alone the delivery address, billing details, delivery date, credit worthiness, quantities ordered, among other items a seller would typically have to agree to before accepting an order. Section 2546 thus simply does not apply by its own terms.

In short, there is no plausible argument that, at the time a replenishment order has been placed, AbbVie no longer has property rights in its own inventory. Forcing it to transfers it drugs at discounted prices to a legislatively-favored third party is a taking. Indeed, if the Attorney General were right, there would be *no need* for Act 358: If title had already vested under Louisiana law because an agreement had been made, then covered entities could simply sue manufacturers for breach of "agreement" referred to in § 2456. No one contends they can do that.

III. THIS COURT SHOULD ENJOIN LOUISIANA FROM ENFORCING THE ACT AS UNCONSTITUTIONALLY VAGUE.

If Act 358 requires manufacturers to transfer heavily discounted drugs, often for a penny, to unlimited numbers of contract pharmacies on demand, then it is preempted, an unconstitutional taking, or both. But to the extent the State argues it requires something *else*, then the statute fails to define the proscribed conduct with adequate specificity, rendering unconstitutionally vague. In

that event, Act 358 both fails to give AbbVie a reasonable opportunity to determine whether its conduct is prohibited and is so indefinite that it authorizes the Attorney General to engage in arbitrary and discriminatory enforcement.

The Fourteenth Amendment's Due Process Clause guarantees that no "State [shall] deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV. "[A]n 'essential' of due process" is "[t]he prohibition of vagueness in criminal [and civil] statutes." *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018); *see also Baggett v. Bullitt*, 377 U.S. 360, 375–79 (1964). From that amendment comes the void-for-vagueness doctrine. That doctrine "proscribes laws so vague that persons 'of common intelligence must necessarily guess at [their] meaning and differ as to [their] application.'" *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 421 (5th Cir. 2001) (quoting *Smith v. Goguen*, 415 U.S. 566, 572 n.8 (1974)). "A law is unconstitutionally vague if it (1) fails to provide those targeted by the statute a reasonable opportunity to know the conduct is prohibited, or (2) is so indefinite that it allows arbitrary and discriminatory enforcement." *Id.* (citation omitted); *see also FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) ("[R]egulated parties should know what is required of them so they may act accordingly" and "precision and guidance are necessary" to avoid arbitrary enforcement).

Act 358 is vague under that standard. It says that "[a] manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity." La. Stat. Ann. § 40:2884(A). Statutes that amorphously prohibit undefined "interference" can run afoul of the vagueness doctrine. *Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023) (law that prohibited "interfer[ing] with or [disturbing] in any way or in any place the students or teachers of any school or college" unconstitutionally vague); *United States v.*

Elliot, 2018 WL 11478272, at *1, 3 (N.D. Ga. Aug. 8, 2018) (regulation that prohibited "[a]ny act or conduct by any person which interferes with, impedes or disrupts the use of the project" unconstitutionally vague as applied); *Corp. of Haverford Coll. v. Reeher*, 329 F. Supp. 1196, 1208-09 (E.D. Pa. 1971) (collecting cases). And here, Act 358 gives no indication of what conduct will be called "interference" with "the acquisition of a 340B drug" under a contract-pharmacy arrangement. La. Stat. Ann. § 40:2884(A).

Gestures at the law of tortious interference with contract, *see*, *e.g.*, Answer ¶¶ 13, 33, do not help. Traditionally, tortious interference means "intentionally and improperly interfer[ing] with the performance of a contract… between another and a third person by inducing or otherwise causing the third person not to perform the contract." Restatement (Second) of Torts §766 (1979). But the analogy is inapt and sheds no light on the meaning of Act 358. If A owns goods and decides not to sell them to B under onerous terms, that does not become tortious interference just because B has a separate contract with C agreeing to acquire them for resale; that is simply an exercise of A's right not to sell. Similarly, just because a covered entity and a contract pharmacy agree to obtain a certain quantity of AbbVie's drugs at below market prices as low as a penny and resell them at full price, AbbVie does not tortiously interfere with that agreement by choosing not to sell and transfer under those terms.

Act 358's vagueness about what it means to "interfere" has real-world consequences. "[M]anufacturer[s] or distributor[s]" currently have numerous and varying restrictions on 340B drug distribution on the books. *E.g.*, *supra* __ (requiring covered entities "submit[] limited claims data" to designate a single contract pharmacy); Gerald Gleeson, *340B Sanofi Covered Entity Letter* (May 15, 2023), https://tinyurl.com/56xa83j9 (requiring "[*n*]*o* claims data . . . for the designated single contract pharmacy location" but instead requiring "designat[ion] through the 340B ESP

platform" (emphasis added)); Novo Nordisk, *Notice Regarding Revised Limitation on Hospital Contract Pharmacy Distribution* (June 1, 2023), https://tinyurl.com/2au2pfrs (authorizing "*all* hospital [covered entities]" "a maximum of *two* [contract pharmacy] designations (one retail and/or one specialty)" (emphasis added)); David Zimmer, *Amgen 340B Covered Entity Letter* (Mar. 17, 2023), https://tinyurl.com/3ux7mbmk (imposing a geographic limitation of "40 miles [from] the covered entity parent site" on the contract pharmacy that "patients may designate [as the] single contract pharmacy location for delivery of 340B-priced drugs"); Kevin Gray, *United Therapeutics 340B Contract Pharmacy Policy Phase 2 Effective Date Delayed From September 1, 2021 to December 1, 2021* (July 23, 2021), https://tinyurl.com/5n8c25tt (rolling out the "contract pharmacy policy" in two phases and authorizing, under the second phase, "340B contact pharmacy orders" where, among other requirements, the covered entity provides "claims data . . . via a platform hosted by a third party with appropriate security and patient privacy safeguards"); *see also* National Association of Community Health Centers, *340B Restrictions Summary Chart* (June 6, 2023), https://tinyurl.com/4c3s7rrv.

Without fair notice to the industry about what counts as "interference," it is impossible to know which of these policies runs afoul of the act and subjects a manufacturer to penalties. That, in turn, leads to impermissible risks of arbitrary enforcement. Absent clarity about the statute's meaning, the Attorney General will be free to cherry pick policies for enforcement actions under Act 358, requiring "the courts to [then] step inside and say who could be rightfully" penalized. *See Dimaya*, 138 S. Ct. at 1228 (Gorsuch, J., concurring) ("A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an *ad hoc* and subjective basis" (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108–09 (1972))).

Act 358's geographic scope is also vague. Act 358 applies to *any* "pharmacy" in the entire United States where "drugs are dispensed and pharmacy primary care is provided to residents of [Louisiana]." La. Stat. Ann. § 37:1164(38) (defining "pharmacy" to "mean[] *any* place located within [Louisiana] where drugs are dispensed and pharmacy primary care is provided, *and any place outside of* [*Louisiana*] where" the same occurs for "residents of [Louisiana]" (emphasis added)); *see* La. Stat. Ann. § 40:2882. As a result, Act 358 could apply to *any* out-of-state pharmacy that provides drugs to a Louisiana resident, for example, via mail-delivery services. Because manufacturers have no way of knowing where individuals treated by a pharmacy may reside, they have no way to ensure their compliance with the Act.

In short, Act 358 either (a) intrudes on a federally preemptive regulatory field, while taking property for private use and without just compensation, or (b) has no readily intelligible meaning, rendering it void under the Fourteenth Amendment. Either way, this Court should enjoin the law.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' motion for summary judgment and issue an injunction enjoining the Louisiana Attorney General from enforcing Act 358.

Dated: January 12, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Defendants' Motion for Summary Judgment and Memorandum in Support thereof was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

/s/ Charles M. Jarrell
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